UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

EDWARD BAKER and JACK MILLER, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

SORIN GROUP USA, INC.

Defendant.

CIVIL ACTION
CLASS ACTION

NO.: 1:16-cv-00260-JEJ
INITIATED: FEBRUARY 12, 2016

PLAINTIFFS' BRIEF IN SUPPORT OF UNOPPOSED MOTION FOR PRELIMINARY APPROVAL OF CLASS ACTION SETTLEMENT

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Plaintiffs, through Class Counsel, submit this Memorandum of Law in support of their Unopposed Motion for Preliminary Approval of Class Action Settlement. At this preliminary stage of the proceedings, the Court need only make a baseline determination that the proposed Class Action Settlement Agreement ("Agreement") is fair and falls within the range of possible final approval. Plaintiffs submit that the proposed Agreement, which is the product of extensive discovery and arms-length negotiations between experienced counsel, satisfies this threshold. Plaintiffs further ask the Court to approve the proposed form and method of Notice of Class Settlement and enter a scheduling order leading to a final hearing.

I. HISTORY OF THE LITIGATION

A. Factual and Procedural History

Plaintiffs, Edward Baker and Jack Miller, initiated this class action by Complaint filed on February 12, 2016, and amended on March 21, 2016. ECF Docs 1 and 8, respectively. Plaintiffs and members of the Class underwent open-heart surgery at WellSpan York Hospital ("WellSpan") or Penn State Milton S. Hershey Medical Center ("Hershey") during an approximate four-year period prior to the filing of the Complaint. ECF Doc. 8. Plaintiffs and the Class allege the intraoperative use of Defendant's Sorin 3T Heater-Coolers ("3T") to heat and cool their blood exposed them to a potentially fatal, slow-growing bacteria known as *M.*

Chimaera.[1] *Id.* The Amended Complaint asserted claims for medical monitoring under Pennsylvania law and a declaratory judgment pursuant to 28 U.S.C. § 2201 that the 3T is defective and unsafe for its intended purpose under Pennsylvania law. *Id.*

On May 20, 2016, Defendant, Sorin Group USA, Inc.,[2] moved to dismiss Plaintiffs' Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6). ECF Doc. 22. By order dated October 11, 2016,[3] this Court found Plaintiffs set forth plausible claims for medical monitoring and declaratory relief. ECF Doc. 46. In doing so, the Court acknowledged that the Class' declaratory judgment claim could be useful in future products liability claims against the Defendant. *Id.* at 15, 17.

On November 2, 2016, the Court set deadlines for expert reports and briefing on class certification. ECF Doc. 53. Thereafter, the parties began extensive discovery, including the production and review of nearly 400,000 pages of Defendant's internal documents, various depositions of Defendant's management-level executives and employees, and expert reports relative to class

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[1] *M. Chimaera* is part of a larger family of bacteria known as non-tuberculous mycobacterium ("NTM").

[2] Subsequent to the initiation of this action, Sorin Group USA, Inc. changed its name to LivaNova Holding USA, Inc.

[3] By Order dated September 29, 2016, this Court granted a separate motion to dismiss by former defendant, LivaNova PLC, pursuant to Fed. R. Civ. P. 12(b)(2). ECF Doc. 45. On March 27, 2019, Class Counsel voluntarily dismissed Defendant, Sorin Group Deutschland GmbH. ECF Doc. 180.

certification. *See* the Declaration of Sol H. Weiss ("Weiss Decl."), which is attached as Exhibit A, at ¶¶ 6-7, 10.

On April 4, 2017, Plaintiffs moved for class certification pursuant to Fed. R. Civ. P. 23(a) and (b)(2). ECF Doc. 60. In support of their motion, Plaintiffs relied on discovery from Defendant's employees and internal documents, independent studies, and independent epidemiological studies. *Id.*

On October 23, 2017, after full briefing by the parties, this Court granted class certification. ECF Doc. 79. The Court certified all Class claims, including the Class' medical monitoring claim (Count I) and its request for a declaratory judgment that the 3T is defective under Pennsylvania law (Count II). *Id.* In its certification order, the Court defined the Class as:

> All individuals who underwent open heart surgery at WellSpan York Hospital between October 1, 2011 and July 24, 2015 or at Penn State Milton S. Hershey Medical Center between November 5, 2011 and November 5, 2015 and who are currently asymptomatic for NTM infection.

Id. at 32.

The certification order further specified that that the Class definition excluded open-heart surgery patients diagnosed with an NTM infection and that the Class' medical monitoring count was certified solely to seek equitable relief. *Id.* at 32-3. With regard to both Class claims, the Court found that certification would allow

the parties to conserve resources and efficiently resolve the factual and legal issues presented by the NTM outbreak allegedly caused by the 3T. *Id.* at 32. [4]

On January 2, 2018, this Court approved the form and method of Notice of Class Certification, which included individualized notice to each Class member's last known home address via first class mail. ECF Doc. 91.

On January 9, 2018, after a conference call with the parties, the Court entered a scheduling order setting trial for August 20, 2018. ECF Doc. 95. Due to scheduling issues raised by Defendant, the Court postponed trial to September 10, 2018.[5] ECF Doc. 98. The parties then engaged in full-scale discovery. Plaintiffs deposed Sorin USA's marketing manager, Shanna Schmidt, account executive, Patricia Monaghan, and a Sorin subsidiary microbiology manager, Paul Talbot. Ex. D (Weiss Decl.) at ¶ 10. Plaintiffs further deposed more than 15 witnesses employed by the hospitals, including the perfusionists who maintained and operated the devices and the infectious disease physicians overseeing the hospitals'

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[4] On November 6, 2017, Defendant petitioned the United States Court of Appeals for the Third Circuit for permission to appeal, which petition was granted on December 13, 2018. Defendant has since dismissed its appeal (ECF Doc. 181), subject to this Court's final approval of the Class Action Settlement for which preliminary approval is now sought.

[5] On March 26, 2018, while expressing that it was "loathe to extend the deadlines", the Court pushed trial to September 17, 2018 to accommodate additional discovery Defendant sought from Hershey but maintained compacted deadlines for dispositive motions and expert depositions. ECF Doc. 124.

medical monitoring programs.[6] *Id.* at ¶¶ 11-12. The parties also participated in on-site inspections of the hospitals' operating rooms and HVAC systems, served requests for admissions, and reviewed voluminous internal documents from WellSpan and Hershey. *Id.* at ¶¶ 13-18, 21. In June and July 2018, the parties exchanged supplemental expert reports bearing on the merits of the Class' claim for medical monitoring and the ultimate issue of whether 3Ts were sold in a defective condition. *Id.* at ¶¶ 22-4. As this Court predicted, the Class' pursuit of their declaratory judgment claim proved to be useful in future claims by other plaintiffs for negligence-based products liability claims against the Defendant (ECF Doc. 46 at 15), including a number of related actions consolidated in MDL 2816[7] and others pending in state courts.

B. Settlement Negotiations

In mid-2018, Class Counsel, Sol H. Weiss, who is also lead Plaintiffs' Counsel in MDL 2816-, was advised that Defendant had retained settlement counsel to discuss the possibility of a resolution of personal injury claims pending in MDL 2816. Ex. D (Weiss Decl.) at ¶ 28. Shortly thereafter, but before a series

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[6] Certain templates from these hospital depositions were shared with plaintiffs' counsel in MDL 2816 for case specific discovery completed at the University of Iowa Hospitals & Clinics in Iowa City, Iowa and Greenville Memorial Hospital in Greenville, South Carolina.

[7] MDL 2816 was created pursuant to a February 1, 2018 Transfer Order from the Judicial Panel on Multidistrict Litigation. *See In Re: Sorin 3T Heater-Cooler Products Liability Litigation (No. II)*, 1:18-cv-MD-2816-JEJ (M.D. PA) at ECF Doc. 56.

of scheduled expert depositions in this Class action, the parties reached an Agreement in principle to settle the Class claims. At the Parties' request, the Court stayed further discovery and vacated the September 2018 trial date. ECF Doc. 171. Class Counsel, also acting in his capacity as Lead Plaintiffs' Counsel in MDL 2816, spent the next several months negotiating the terms of settlement with the Defendant. Ex. A (Weiss Decl.) at ¶ 29. The proposed resolution of the Class claims is the product of extensive arms-length negotiations, legal and factual research and due diligence with the assistance of non-parties WellSpan and Hershey. The terms and conditions of the proposed Class Action Settlement, which Class Counsel believe are fair and reasonable in all respects, are set forth in the Agreement, which is attached as Exhibit B.

Despite a strong belief in the merits of the Class claims, Plaintiffs recognize that there are substantial uncertainties and significant litigation costs associated with the pursuit of this Class action through trial. Moreover, as discussed in more detail below, the terms of the Class Action Settlement coupled with the recent agreement for settlement of personal injury claims obviate the need for a trial on the Class claims. After thoroughly analyzing the facts and the law, Plaintiffs have determined that the Agreement represents a fair and reasonable resolution that provides significant benefits to the Class.

While denying any liability relative to the Class's potential exposure to NTM and maintaining that the 3T is safe and effective, Defendant also considers it desirable that the Class action be settled so as to avoid the substantial expense of ongoing litigation and uncertainties of trial. For these reasons, the Parties believe it is in their best interests, and in the best interest of the Class, to resolve the Class claims under the terms presented.

C. Basic Terms of the Proposed Settlement

The Agreement fully resolves all Class claims, including the Class' claims for medical monitoring and declaratory relief. The Agreement's treatment of each claim, as well as any attorney fee award, incentive awards, and Class Notice is summarized below.

i. Medical Monitoring

Under the terms of the Agreement, both WellSpan and Hershey will continue providing free medical monitoring to all Class members for a minimum of 5 years following the date of their respective open-heart surgeries.[8] Ex. B (Agreement) at ¶ II(A). The existing medical monitoring protocols, which were developed by the infectious disease physicians and leadership of WellSpan and Hershey and have been deemed adequate by Plaintiffs' infectious disease expert,

[8] This term ensures that Class members will receive medical monitoring throughout the average latency period for *M. Chimaera* infections following open-heart surgery.

John J. Stern, M.D., will govern future monitoring. *Id.* at ¶ II(B). The proposed resolution of the Class' medical monitoring claim ensures that Class members will receive necessary and free monitoring for the full duration of the latency period.

ii. Declaratory Relief

Before and after class certification, Class Counsel collectively devoted 1,992 hours and significant resources[9] towards uncovering and developing essential facts that Class Counsel believes would warrant a jury to conclude that 3Ts left Defendant's manufacturing site in an unreasonably dangerous and defective condition under Pennsylvania law. Ex. A (Weiss Decl.) at ¶ 30. Class Counsel also believes its efforts to establish liability were a motivator for Defendant to entertain a settlement of personal injury claims.

The resolution of the Class' declaratory judgment claim benefits all Class members, who are eligible to continue receiving medical monitoring. And Class Counsel's efforts in preparing the declaratory judgement claim for trial also benefits all plaintiffs with related personal injury and wrongful death actions consolidated in this Court for pre-trial purposes under MDL 2816, including

[9] The time and expenses included in this submission and recognized in the Agreement relate solely to *Baker v. Sorin Group Deutschland GmbH, et al.* and are exclusive of the time and expenses expended by Anapol Weiss for its individual personal injury actions and role as Lead Plaintiffs' Counsel in MDL 2816. The deposition transcripts, work product and expert reports from *Baker* were shared with plaintiffs' counsel in the MDL and certain plaintiffs' counsel in state court actions.

former Class members diagnosed with NTM infections who are eligible to receive settlement compensation under the terms of a global settlement structure agreed to by Defendant on March 28, 2019 and Class members diagnosed with NTM infections in the future, who also may enter separate personal injury settlements. The Agreement recognizes that the extensive discovery completed in this declaratory judgment action and shared with all MDL plaintiffs' counsel facilitated the resolution of the MDL actions. The Class has thus agreed to resolve their declaratory judgment claim because the global settlement of the MDL actions obviates the need for a jury trial to determine if the 3T is defective.

iii. Attorneys' Fees, Expenses and Incentive Awards

Pursuant to the Agreement, Defendant should not be opposing an application by Class Counsel for a reasonable and appropriate fee award, if made. Ex. B (Agreement) at ¶ V. It is anticipated that any future fee petition would address the successful pursuit of the instant Class Action and the significant effect this case had in facilitating the global resolution of MDL 2816 support a fee request under the substantial benefit and common fund doctrines. . Ex. B (Agreement) at ¶ V. The Agreement further provides for a reimbursement from the MDL Executive Committee to the Class for generic litigation expenses in the amount of $128,310.46 and an application for reasonable and appropriate incentive awards for Class representatives, Edward Baker and Jack Miller, in recognition of their

cooperation throughout the discovery process, which included lengthy depositions and discovery responses that disclosed their personal medical information. Ex. B (Agreement) at ¶ V.

iv. Class Notice of Settlement

The parties have agreed upon a proposed Notice of Class Certification, Preliminary Approval of Proposed Class Action Settlement and Final Approval Hearing (attached as Exhibit C)("Notice of Proposed Class Action Settlement"), which they believe satisfies the due process considerations of Fed. R. Civ. P. 23(c) by providing Class members with adequate information about how their legal rights are affected by this litigation and the proposed Class Action Settlement. The parties propose that the Notice of Proposed Class Action Settlement be disseminated to Class members individually via first class mail. Ex. B (Agreement) at ¶ VII(A); *see also* Annotated Manual for Complex Litigation § 21.311 (4th ed. 2011)(individual notice widely considered to be the best notice practicable); *Fry v. Hayt*, 198 F.R.D. 461, 474 (E.D. Pa. 2000)(same). Additionally, a copy of the Notice of Proposed Class Action Settlement will be posted to Class Counsel, Anapol Weiss', website at https://www.anapolweiss.com/ntm-class-action/ where a document depository for the Class is maintained. Ex. B (Agreement) at ¶ VII(A).

II. STANDARD OF REVIEW

Fed. R. Civ. P. 23(e) governs the settlement of class actions and the procedures applicable to the review of a proposed class action settlement. Preliminary approval of a proposed class action settlement "establishes an initial presumption of fairness" and guides "whether notice of the proposed settlement should be sent to the class." *Basile v. Stream Energy Pennsylvania, LLC*, 2018 WL 2441363, *2 (M.D. Pa. May 31, 2018)(citing *In re GMC Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 785 (3d Cir. 1995), *cert. denied*, 516 U.S. 824; Newberg on Class Actions § 11.41 (3rd ed.); Newberg on Class Actions § 13:13 (5th ed.).

In deciding whether to grant preliminary approval, a court must determine: 1) whether the proposed settlement discloses grounds to doubt its fairness or other obvious deficiencies such as unduly preferential treatment of class representatives or segments of the class, or excessive compensation of attorneys; and 2) whether it appears to fall within the range of possible approval. *In re Nat'l Football League Players' Concussion Injury Litig.*, 301 F.R.D. 191, 197–98 (E.D. Pa. 2014)(citing *Mehling v. New York Life Ins.*, 246 F.R.D. 467, 472 (E.D. Pa. 2007)(citations omitted); *Mack Trucks, Inc. v. Int'l Union*, UAW, 2011 WL 1833108, *2 (E.D. Pa. 2011); *Tenuto v. Transworld Sys.*, 2001 WL 1347235, *1 (E.D. Pa. 2001)). The law favors settlement, particularly in class actions and other complex cases where

substantial judicial resources can be conserved by avoiding formal litigation. *In re GMC Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d at 784.

III. The Proposed Class Action Settlement Should be Preliminarily Approved

i. No Obvious Deficiencies Cast Doubt on the Fairness of the Proposed Class Action Settlement

Settlements that occur after meaningful discovery and extensive "arms-length negotiation" by competent counsel are presumed to be fair. Newberg § 11.41; *see also In re GMC Pick-Up Truck Fuel Tank Prods. Liability Litigation*, 55 F.3d at 785; *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 539-40 (3d Cir. 2004); *In re Cendant Corp. Litig.*, 264 F. 3d 201, 233 n. 18 (3d Cir. 2001); *Petruzzi's, Inc. v. Darling-Del. Co.*, 880 F. Supp. 292, 301 (M.D. Pa. 1995). The Agreement reached here is entitled to a presumption of fairness because it is the product of extensive arms-length negotiations undertaken in good faith for nearly six months. Significant discovery has been completed over the course of this nearly three-year litigation, including expert reports bearing on the merits of the Class' request for a declaration of device defect. *See* Section I.A. *supra*. Moreover, the Agreement was negotiated by counsel with extensive experience in complex litigation, including Class Counsel who has zealously advocated for the Class' interests.

The Agreement does not provide for preferential treatment of any individual Class Member because each Class member is equally entitled to participate in the free medical monitoring program. Ex. B (Agreement) at ¶ II(A); *see also In re Nat'l Football League Players' Concussion Injury Litig.*, 301 F.R.D. at 199 (granting preliminary approval of settlement that did "not appear to provide undue preferential treatment to any individual Settlement Class Member or Subclass.") Reasonable incentive awards for Class Representatives, Edward Baker and Jack Miller, do not amount to preferential treatment. *Pfeifer v. Wawa, Inc.*, 2018 WL 2057466, *6 (E.D. Pa. 2018)(finding an incentive award of $25,000 for each named plaintiff was not facially unreasonable); *Cullen v. Whitman Med. Corp.*, 197 F.R.D. 136, 145 (E.D. Pa. 2000)("Courts routinely approve incentive awards to compensate named plaintiffs for the services they provided and the risks they incurred during the course of the class action litigation.").

Finally, any reasonable and appropriate attorney's fees that Class Counsel may seek in a future fee petition should acknowledge that Class Counsel assumed a significant risk of non-payment, devoted nearly three years and substantial resources to the development and prosecution of the Class claims, and secured a beneficial resolution of the Class claims. Moreover, it is uncontested that Class Counsel's development of the Class' declaratory judgment claim facilitated a global settlement of more than 100 related products liability actions consolidated in

MDL 2816, certain State Court actions where plaintiffs' counsel agreed to use the MDL work product for 2% of the gross award, and other State Court actions not subject to any assessment. *In re: Diet Drugs*, 582 F. 3d 524, 541 (3rd Cir. 2009)(citing *Gunter v. Ridgewood Energy Corp.*, 223 F.3d 190, 195 (3d Cir. 2000); *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 336 (3d Cir. 1998)(in reviewing the reasonableness of fee awards courts look to factors such as risk of non-payment, the complexity and duration of the litigation, and the value of the benefit attributable to class counsel); *see also Bredbenner v. Liberty Travel, Inc.*, 2011 WL 1344745, *21 (D.N.J. Apr. 8, 2011)(citing *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d at 822)(noting that in the Third Circuit reasonable attorney's fees generally range from 19% to 45% of the common fund); Newberg on Class Actions § 15:108 (5th ed.)(the substantial benefit doctrine arises when an attorney retained by one client secures a benefit for a group of clients—but the benefit is non-monetary in nature and no fee-shifting statute applies). The Court retains authority to determine any final attorneys' fee and cost award. *In re Rite Aid Corp. Securities Litig.*, 396 F.3d 294, 299 (3d Cir. 2005)(citations omitted).

ii. The Proposed Class Action Settlement Falls Well Within the Range of Approval

Under Rule 23, a settlement falls within the "range of possible approval" if there is a conceivable basis for presuming that the standard applied for final

approval—fairness, adequacy, and reasonableness—will be satisfied. *In re Nat'l Football League Players' Concussion Injury Litig.*, 301 F.R.D. at 198 (citing *Mehling*, 246 F.R.D. at 472). In assessing whether the settlement falls within the range of possible approval, the Court must also consider plaintiffs' expected recovery balanced against the value of the settlement. *Basile*, 2018 WL 2441363 at *6 (citing *In re Nat'l Football League Players' Concussion Injury Litig.*, 961 F. Supp. 2d 708, 714 (E.D. Pa. 2014)).

Here, there is a strong basis upon which to conclude the standards for final approval will be met. Seven of the nine factors that will be evaluated at a final fairness hearing are applicable to this preliminary determination: 1) the complexity, expense and duration of litigation; 2) the stage of the proceedings and amount of discovery completed; 3) the risks of establishing liability and damages; 4) the risks of maintaining the class action through trial; 5) the ability of the defendant to withstand a greater judgment; 6) the range of reasonableness of the settlement fund in light of the best possible recovery; and 7) the range of reasonableness of the settlement fund in light of all the attendant risks of litigation. *In re Flonase Antitrust Litig.*, 951 F. Supp. 2d 739, 742 (E.D. Pa. 2013)(citing *Girsh v. Jepson*, 521 F.2d 153, 157 (3d Cir.1975); *see also Martin v. Foster Wheeler Energy Corp.*, 2007 WL 4437221, *5 (M.D. Pa. Dec. 2007).

A thorough analysis demonstrates that, at this preliminary stage, there is ample reason to conclude that the Agreement will satisfy the standard for final approval. The complexity, expense, duration and amount of discovery completed in this Class Action weigh heavily in favor of preliminary approval. This action has been pending for over three years, concerns complex products liability questions that would require extensive and expensive expert testimony at trial, and discovery was substantially completed when the Parties reached the proposed Agreement. The Class Action Settlement was achieved when the parties had a clear view of the issues involved and the strengths and weaknesses of their respective positions. While Plaintiffs are confident that they would maintain class action status and the Class claims would be successful at trial based on the discovery, motion practice and expert reports, the additional time, expense, and uncertainties of trial are outweighed by the value of resolving the Class claims under the terms presented.

The proposed settlement satisfactorily resolves both Class claims, because it ensures that Class members will continue to receive free medical monitoring, and acknowledges settlement of related personal injury and wrongful death actions rendering it unnecessary to further pursue the Class' request for a declaration that the 3T is defective. Given the equitable nature of the relief obtained through the proposed Agreement, it is difficult to imagine a better possible recovery at trial.

The proposed Agreement thus satisfies Plaintiffs' expected recovery. *Basile*, 2018 WL 2441363 at *6.

The proposed settlement also falls within the range of possible approval because courts throughout the country have approved settlements in similar medical monitoring actions. *See e.g., In re Nat. Football League Players' Concussion Injury Litig.*, 307 F.R.D. 351, 378 (E.D. Pa. 2015), *judgment amended*, 2015 WL 12827803 (E.D. Pa. May 8, 2015)(granting final approval of medical monitoring class action settlement); *In re Diet Drugs Prods. Liab. Litig*, 2000 WL 1222042, *69 (E.D. Pa. Aug. 28, 2000)(granting final approval of medical monitoring class action settlement); *In re Inter-Op Hip Prosthesis Liability Litig.*, 204 F.R.D. 330 (N.D. Ohio 2001)(granting preliminary approval of a settlement in medical monitoring action concerning a medical device); *In re Nat'l Collegiate Athletic Ass'n Student-Athlete Concussion Injury Litig.*, 314 F.R.D. 580, 608 (N.D. Ill. 2016)(granting preliminary approval of medical monitoring class action settlement).

IV. CONCLUSION

For all the foregoing reasons, Plaintiffs request that the Court grant preliminary approval of the proposed Class Action Settlement, approve the proposed form and method of Notice of Proposed Class Action Settlement, and issue a scheduling order relative to a final hearing.

Dated: October 11, 2019

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CERTIFICATE OF WORD COUNT PURSUANT TO LOCAL RULE 7.8

I, Sol H. Weiss, Esquire, hereby certify that the foregoing brief complies with the word count limitation set forth in Local Rule 7.8. According to the word count feature of Microsoft Word, the brief contains a total of 3,912 words, including textboxes, footnotes and endnotes.

ANAPOL WEISS

/s/ Sol H. Weiss
Sol H. Weiss

CERTIFICATE OF SERVICE

I, Sol H. Weiss, Esquire, hereby certify that on October 11, 2019 the foregoing Brief in Support of Plaintiffs' Unopposed Motion for Preliminary Approval of Class Action Settlement was filed and made available to all counsel of record via CM/ECF.

ANAPOL WEISS

/s/ Sol H. Weiss
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